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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/606,137	06/28/2000	Michael E. Moseley	500.003US1	5608

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EXAMINER

LIN, JEYUHU

ART UNIT

PAPER NUMBER

3737

DATE MAILED: 09/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/606,137

Applicant(s)

MOSELEY ET AL.

Examiner

Jeoyuh Lin

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 and 47-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-43 and 47-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Entry of Amendment

1. Applicant's amendment, filed on February 25, 2002, as paper No. 9, is acknowledged. Claims 1-43, and 47-49 are currently pending.

Claim Objections

2. Claim 31 is objected to because of the following informalities: Claim 31 is claimed to be dependent on itself. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

-Claims 1-43, and 47-49 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an MRI method, does not reasonably provide enablement for a sensing method that detect the viability of implanted stem cells, progenitor cells, or differentiated cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claimed invention is drawn to methods of indicating viability of "implanted cells, progenitor cells, or differentiated cells". However, there is very limited guidance within the specification as to how this is to be accomplished. The claimed methods (referring to the broadest claim) require a "sensing" function of cells within a region of a patient. The specification at page 5, beginning on line 18 indicates that "no disclosures

Art Unit: 3737

are known that provide a method or device for...non-invasively monitoring the physiologic and metabolic status of a cell implant". Continuing on page 5, at line 24, the specification states that the "present invention provides an MR imaging method...". However, at least the broad claim is drawn to any sensing method and is not limited to MRI methods. Therefore, a breadth issue exists regarding the scope of the disclosure versus the "sensing" function set forth in the claimed invention.

In discussing the MRI methods, art-recognized metabolic changes are to be assayed. These include such things as observing GABA, PCr, creatine, choline, and lactate metabolites (page 6, lines 4 and 5). The specification also discusses labeling strategies with such markers as C13, F19, N14, S33, H2, Mg, Fe, and other MR-sensitive nuclei (Pg 6 and 7). It is acknowledged that these types of markings are known in the art. However, the claimed invention requires an analysis of very specific type of cells (i.e. stem cells, progenitor cells, and differentiated cells and such general labels while viewable via MRI are not cell type specific). Once a cell is introduced within a host, unless there is some discernable factor which can be specifically detected, (whether it be metabolic, anatomic, or labelable), the cell is inseparable from surrounding cells. In the instant case, the cells are of specific types and the specification fails (with one exception) to provide any guidance as to how one would detect them.

On page 29, beginning at line 3, the specification indicates that, "the ability to monitor correct cell placement non-invasively with MR imaging is currently not available." The specification then goes on to state that in a preferred embodiment, MR

is used to detect cells that have been labeled with a detectable marker (in this case Green Fluorescent protein, GFP). This is the only guidance present in the as filed specification as to how to detect a particular cell that has been implanted into a host.

Given the paucity of guidance regarding any inherent property (metabolic, anatomic, or labelable) of stem cells, progenitor cells, it would seem that the claimed methods should be limited to the detection of cells that have been specifically labeled or marked prior to implantation. The concept of the disclosed invention is that one can then find such cells using non-invasive MRI methods, which could be enabling. Thus, there is at least a prima facie case that the claimed methods should be limited to MRI methods and the use of ex-vivo-labeled cells where the label is suitable for MRI methods. Note however, that cells used for implantation have been marked in the prior art for some time using things such as metabolic and other markers (including drug resistance markers and GFP (as disclosed in provisional US patent 60/082,941). Therefore, a prior art issue may be raised based upon whether or not the prior art would have expected to be able to detect, at least, GFP-marked cells.

In summary, the specification fails to provide and general guidance as to how to detect specific cells within a host that do not have MRI detectable properties, and it also fails to teach what such properties would be for any stem cell, any and all "progenitor cells", and any and all "differentiated" cells.

Response to Arguments

4. Applicant's arguments with respect to claims 1-43, and 47-49 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeoyuh Lin whose telephone number is (703) 306-5990. The examiner can normally be reached on m-f, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marvin Lateef can be reached on (703) 308-3256. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0758 for regular communications and (703) 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

JYL

JYL
September 4, 2002



Marvin M. Lateef
Supervisory Patent Examiner
Group 3700